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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,766	06/27/2003	David Wynn	MCP-5014 NP	7412
27777	7590	12/05/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,766	<b>Applicant(s)</b> WYNN ET AL.	
	<b>Examiner</b> James W. Rogers, Ph.D.	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-12 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12 and 15-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The 112 second paragraph rejection for claims 18 which depends upon claim 9 has been withdrawn in view of applicants response dated 11/14/2006, there was support for a hydroxyalkylcellulose in claim 8 from which claim 9 depended upon.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5,7-12 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buehler et al. (US 6,432,442 B1, cited by applicant) in view of Roche (US 5,075,114, cited by applicant) in view of Wong et al. (5,532,244) and in further view of Dressman et al (US 5,789,393), for the reasons set forth in the previous office action dated 08/10/2006.

Applicants arguments filed 11/14/2006 have been fully considered but are not persuasive.

Applicants asserts that Bueler fails to disclose or suggest the particular hydroxyalkylcellulose as claimed in claim 1.

The relevance of this assertion is unclear, from the previous office action dated 08/10/2006 the examiner already noted that Bueler does not disclose the MW and viscosity in 2% aqueous solution of HPC, that is why the examiner combined Bueller in a 103(a) rejection. The examiner relied upon Dressman to show that HPC within the MW and viscosity as claimed by applicant was already well known at the time of the invention. Since the Bueler reference is used in combination with the secondary references Bueller on it's own does not have to disclose every single limitation of applicants claimed invention as long as the combination meets applicants claimed invention and it would have been obvious to one with skill in the art to combine those references.

Applicants assert that Roche fails to disclose or suggest the use of a hydroxyalkylcellulose in the dosage for matrix as claimed.

The relevance of this assertion is unclear, since the Roche reference is used in combination with the primary reference Bueler, which does disclose the use of a hydroxyalkylcellulose, it does not have to disclose every single limitation of applicants claimed invention as long as the combination meets applicants claimed invention and it would have been obvious to one with skill in the art to combine those references. Roche as disclosed in the previous office action disclosed chewable tablets containing

granules of enterically coated ibuprofen, coated by a blend of CA and hydroxypropyl cellulose, an obvious derivative of HPMCP, were well known at the time of the invention.

Applicants asserts that the examiner does not point to the location within Wong that supports the statement "Wong is used only to show that HPMCP [is] an obvious derivative of HPC".

This statement was not written as above, the word [is] was not included in the original document and therefore the statement had a different meaning than what applicants interpreted, the examiner only meant that HPMCP and HPC are obvious derivatives of each other, it was never stated in the office action that Wong stated that they were obvious derivatives. By combining Roche and Wong one skilled in the art could have envisioned applicants claimed invention because Roche discloses an enteric coating of a blend of CA and HPC and Wong discloses the use of HPMCP in enteric coating, HPC and HPMCP are obvious derivatives of each other as stated by the examiner and would be interchangeable.

Applicants then state that Wong does not disclose the use of a hydroxyalkylcellulose in the dosage form matrix as claimed.

The relevance of this assertion is unclear, since the Wong reference is used in combination with the primary reference Bueler, which does disclose the use of a hydroxyalkylcellulose, it does not have to disclose every single limitation of applicants claimed invention as long as the combination meets applicants claimed invention and it would have been obvious to one with skill in the art to combine those references.

Applicants state the Dressman fails to disclose or suggest the use of cellulose ethers in the matrix dosage form wherein such dosage form contains "a plurality of particles comprising a pharmaceutically active ingredient", instead Dressman discloses the use of cellulose ethers as active ingredients in the dosage form.

The relevance of this assertion is unclear, Dressman is used primarily to show that HPC within applicants claimed MW and viscosity range was already known to be used in dosage forms. Since the Dressman reference is used in combination with the primary reference Bueler, which does disclose the use of a hydroxyalkylcellulose in a matrix dosage form, it does not have to disclose every single limitation of applicants claimed invention as long as the combination meets applicants claimed invention and it would have been obvious to one with skill in the art to combine those references.

Applicants finally state that the combination of the references above would still lack the particular claimed hydroxyalkylcellulose (having the same MW and viscosity) in the matrix of a dosage form.

The relevance of this assertion is unclear, from the above arguments the examiner believes it is clear that the combination of the references above would meet all of applicants currently claimed invention, including a hydroxyalkylcellulose within the claimed MW and viscosity range.

### ***Conclusion***

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER